REMARKS

Reconsideration of the present application in view of the foregoing amendments and the following arguments is respectfully requested. Applicant has cancelled claims 1-5, 45-50 and 63-69 to focus consideration on independent claim 51 and its dependent claims 52-62.

Applicant first requests withdrawal of the finality of this Office Action. As stated in the Office Action, Applicants' prior arguments for patentability over the previously cited art were deemed moot in view of the new grounds of rejection. Applicants' amendments in that response did not necessitate the new rejections, since original unamended claims 1-5 were subject to the same rejections as the new claims. It is apparent that Applicants' arguments were sufficient to overcome the original rejections. Since those arguments were mooted by the new grounds for rejection, Applicants should be provided with the opportunity to fully argue for the patentability of the present claims over the applied references.

Claim 51 was rejected as anticipated by the patent of Mirza. The Mirza patent was cited as disclosing the insertion of a tool into a bone and swinging the tool through an arc to form a cavity that has an area larger than the tool body. The Mirza device is operable to form a spherical or cylindrical cavity within a bone (FIG. 10) or in the intervertebral space between vertebral bones (FIGS. 17-25. The cutting tip 14 of the Mirza tool 10 is freely rotatable, or passively hinged, relative to the shaft 12 of the tool. Col. 4, lines 19-24, 33-38. After insertion into the bone, the shaft is rotated at a very high speed (40,000+ rpm) so that centrifugal force acts on the cutting tip to cause it to swing off the centerline in a conical configuration. Col. 5, lines 24-32. Eventually the centrifugal force will move the cutting tip to the perpendicular orientation depicted in FIG. 10, liquefying the bone to produce a semi-spherical cavity 44. Col. 5, lines 32-37.

The Mirza patent fails as an anticipatory reference for several reasons. First, the method of Applicants' claim 51 is for creating a transverse cavity in a bone having a compression fracture. There is no disclosure in Mirza of the use of the tool 10 to create a cavity in a fractured bone. Moreover, given that the cutting tip 14 of the Mirza tool is rotating at an extremely high speed and that it necessarily forms a cylindrical or spherical cavity, it is uncertain whether such a device could be used at all in a bone that has suffered a compression fracture.

Second, Applicants method calls for identifying a surface that is to be restored to its normal anatomic position. This step was ignored in the Office Action when the Mirza was being applied to Applicants' claims. The Mirza patent describes no such step. The primary stated purpose of the Mirza

tool is for the replacement of osteoporotic bone with a material of increased strength. Col. 1, lines 63-67. Other purposes are described at col. 2, lines 50-64, none of which concern restoring a bone to its normal anatomic position.

Furthermore, there is nothing in Mirza that discloses identifying a bone surface that defines a transverse plane. Since Mirza does not disclose this step it cannot disclose the next step of Applicants' claim 51, namely the step of inserting a tool into the bone adjacent the surface that defines the transverse plane. Instead, use of the Mirza device requires maintaining a "safe zone" between the cutting head and the outer surface of the bone. Col. 5, lines 45-50.

Applicants' claim 51 further defines the step of activating a movable element operably supported by the tool. As disclosed in the specification of the present application, this application involves affirmatively moving the movable element, such as by pushing the actuator rod 32 to rotate the cutting blade 38 depicted in FIG. 2. As explained above, the Mirza cutting tip 14 is passive and moves only under operation of centrifugal force as the tool shank 12 is rotated.

Even if the Mirza cutting tip can be considered to be "activated", it is clear that the Mirza cutting tip does not move in a direction outwardly from the tool body and "substantially parallel to said surface", namely the surface defining the transverse plane, to "define a transverse cavity". As explained above, the cutting tip of Mirza necessarily moves in an ever-increasing diameter cone as it spins initially along the longitudinal axis and then gradually, under influence of centrifugal force, deviates from that axis to form the cone. Since Mirza does not contemplate a surface of a bone defining a transverse plane, there is no frame of reference for the movement of the cutting tip – i.e., there is nothing for the cutting tip to move parallel to. Moreover, since the Mirza cutting tip can only form either a cylinder (46 in FIG. 12) or a semi-spherical cavity (44 in FIG. 11) it cannot define a transverse cavity. Applicants' claim 51 further defines the transverse cavity as having a substantially uniform height in a direction perpendicular to the transverse plane. Again, since there is no transverse plane defined in Mirza there is no frame of reference for measuring the height of a transverse cavity. Moreover, the Mirza cutter must at least initially form a semi-spherical cavity, so there is no transverse cavity having a substantially uniform height.

The Mirza reference fails to identically disclose any element recited in Applicants' claim 51. In order to more clearly define Applicants' claimed method, claim 51 has been amended to define the activation of the movable element "through a path consisting essentially of a substantially flat plane that is substantially parallel to said surface", which surface defines the transverse plane. This language

is supported throughout the specification in which the cutting blade only moves transversely, or in a substantially flat plane. See, e.g., FIG. 2. The cutting tip 14 in Mirza does not move in a flat plane.

The Mirza reference does not anticipate claim 51 because it fails to disclose every limitation in that claim. Moreover, there is no suggestion or motivation to modify the device or procedure disclosed in Mirza in a manner that would meet every limitation of Applicants' claims. In order for Mirza to meet claim 51, it would be necessary to make the cutting tip 14 active rather than passive. It would thus be necessary to modify the Mirza tool to connect some form of actuator to the cutting tip to deliberately move the tip in a flat plane. Of course, in so doing it would also be necessary to hold the shank 12 of the Mirza tool stationary, rather than rotate it at the 40,000+ rpm disclose in that reference. In short, any modification to the Mirza tool and procedure to meet Applicants claimed invention would completely destroy the tool as it was disclosed and contemplated in the Mirza Patent.

It is therefore believed that Applicants' claim 51 is neither anticipated nor rendered obvious by the Mirza patent. The dependent claims to claim 51 also enjoy the benefit of the allowability of this parent claim over the art of record. Moreover, these claims are also allowable over the cited art on their own merits. For instance, claim 52 defines the movable element as a pivotably mounted blade. The cutting tip in Mirza is not a blade, as is apparent from FIGS. 6-7. It can be surmised that the cutting tip in Mirza must have the configuration depicted in those figures in order to withstand the forces exerted during rotation at 40,000 – 80,000 rpm.

Claim 56 defines the rotational activation of the movable element, or blade, occurring by a push-pull motion. In response, the Nallakrishnan was combined with the Mirza reference. First, as explained above, any modification to Mirza to permit positive actuation of the cutting tip would completely frustrate the entire purpose of the Mirza tool. Second, the knob, pin and track of Nallakrishnan are only operable to push the surgical knife out of the case 11 and hold it in its extended position. Col. 3, lines 45-63. Adjustment of the angle of the blade is accomplished by manually pivoting the bladeholder 16 at the end of the tool 10. Col. 4, lines 10-29, 40-53. The knob 20, pin 31 and track 28 have no effect on the angular position of the blade. Contrary to the assertion in the Office Action, there is nothing in the Nallakrishnan reference that discloses or contemplates activating rotational motion of a blade by a push-pull action. Thus, claim 56 should be allowable over the cited references.

Claim 58 defines the transverse cavity as having an oval-shaped area. This claim was rejected as obvious in view of the combination Mirza with the patent of Johnson. There is nothing in either

reference that discloses an oval transverse cavity. It was suggested in the Office Action that "one of ordinary skill in the art would know that the transverse cavity could be oval shaped or asymmetric about a vertical axis" and that it would "depend on the desired shape that the medical attendant wants to form in the body." There is no support at all for these suppositions as to what a person of skill in this art would contemplate. All of the devices disclosed in the cited references create circular or spherical cavities. There is no motivation in any of these references to deviate from these standard and easily achievable shapes. Unlike Applicants' claimed invention, none of the cited references contemplates creating a transverse cavity for the purpose of restoring a bone having a compression fracture to its normal anatomic position. As explained in the specification, this restoration may require controlling the shape of the cavity to direct expansion to preferred areas of the fractured bone. See, e.g., para. 43, 47. None of this motivation is present in the art of record.

Claims 59 and 60 define the types of compression fractures treated according to the recited method steps of claim 51. These claims were also rejected as obvious in view of the combination of Mirza and Johnson; however, there is no explanation supporting the rejection of these particular claims. Certainly, none of the cited references disclose a compression fracture of any type, so they cannot be said to contemplate or suggest treatment of the various types of fractures defined in claims 59 and 60. Furthermore, as explained above, the fact that the Mirza tool forms a semi-spherical or cylindrical cavity by high speed rotation of the cutting tip would seem to militate against the use of the Mirza tool in a bone that has suffered a compression fracture.

Claims 61 and 62 define entry points for the treatment of a vertebral compression fracture. As explained above, none of the cited references discloses a compression fracture, let alone a vertebral compression fracture. Thus, there is no motivation to suggest any particular entry point for the treatment, let alone the pedicle and transpedicular approach defined in claims 61 and 62. While the Mirza patent does discuss certain spinal treatments, they are all intervertebral, not intra-vertebral.

Finally, Applicants have presented new claim 70 that depends from allowable claim 51. Claim 70 recites that the tool body is maintained in a fixed position relative to rotation about its longitudinal axis. Since the movable element of the present invention is operable to form a transverse cavity having a substantially uniform height, the tool cannot be permitted to rotate about its longitudinal axis. This feature is in direct contrast to the Mirza device that requires rotation of the tool body supporting the movable element or cutting tip.

In view of the foregoing arguments and amendments, it is believed that withdrawal of the rejection of claims 51- 62 is appropriate. Applicants also request allowance of newly added claim 70. This application is otherwise believed to be in condition for allowance. The Examiner is invited to contact the undersigned if there are any further issues that can be readily addressed in a telephonic interview.

Respectfully submitted,

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